DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

m3910n

WARNING LETTER
VIA FEDERAL EXPRESS

JUN 29 2000

Mr. Phillipe Pontieux
Plant Manager
Dimequip
Route de Bavay
7080
Frameries, Belgium

Dear Mr. Pontieux:

During the Food and Drug Administration's (FDA) inspection of your plant, Dimequip, located at Route de Bavay, 7080 Frameries, Belgium, from April 25-28, 2000, Thierry Thomas, CAB Auditor, and FDA investigator Ta Thao determined that your firm manufactures disposable infant feeding tubes, scalp vein sets, cannulas and catheters. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated, in that the methods used in, or the facilities or controls used for the manufacture, packaging, storage, or installation are not in conformance with the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820, as follows:

1. Failure to establish and maintain procedures for implementing corrective and preventive action including investigating the cause of non-conformities relating to product, processes, and the quality system, as required by 21 CFR 820.100(a)(2). For example, corrective action activities do not include investigating the cause of defects, such as tubing coming out of the hub, that are related to the [redacted] injection process.

Our review of the [redacted] injection process revealed that there were at least two defects identified. This information was also included in a document for management review, dated January 26, 2000. There was no documentation of investigation to determine the root cause of the problems, nor was there written justification why an investigation was not warranted.

2. Failure to verify or validate corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CFR 820.100(a)(4). For example, the design changes made for the [redacted] catheters were neither verified or validated to ensure that the changes were effective and did not have an adverse effect on the device.

You became aware of a hub-cracking problem caused by the hub's incompatibility with [redacted] infusions. In September 1996, the design changes for the catheter hub raw material and a switch from a [redacted] to an [redacted] process were implemented. Between 1997 and 1999, 24 complaints were received by your parent firm, Vygon Ecouen regarding hub cracking. An investigation of the complaints revealed the problem was hub incompatibility with [redacted] and [redacted]. The changes to the device were not verified or validated to ensure that they were effective to prevent recurrence of the problem.

3. Failure to develop, maintain, and implement written MDR procedures as required by 21 CFR 803.17. For example, although you have procedures in place for complaint handling, there are no written procedures that address the requirements of the written MDR procedures such as timely and effective identification, communication, and evaluation of events that may be subject to medical device reporting requirements. Additionally, there is no standardized review procedure or timely transmission to FDA. Your QA/QC manager confirmed this finding

This letter is not intended to be an all-inclusive list of deficiencies at you facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FD-483 issued a the conclusion of the inspection may be symptomatic of problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violation identified by the FDA. If the causes are determined to be a systems problem, you must promptly initiate permanent corrective action.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Please notify this office in writing within 15 days of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problem necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If documentation is not in English, please provide an English translation to facilitate our review. Please address your response to Paul F. Tilton, Acting Branch Chief, OB/GYN, Gastroenterology, and Urology Branch, Division of Enforcement II, HFZ-332 at the above address.

If you have any questions, please contact Sharon Murrain-Ellerbe at the above address or at (301) 594-4616 or FAX (301) 594-4638.

Sincerely yours,

Steven M. Niedleman
Acting Director
Office of Compliance
Center for Devices and
Radiological Health